

### REMARKS/ARGUMENT

Claim 95 has been rejected under 35 U.S.C. § 112, first paragraph. Applicant expects to add dependent claims to this application upon a general understanding on the nature and scope of the claim in this response. Support for the amended claim may be found throughout the specification, specifically page 10 lines 13-21.

#### **Rejections Under 35 U.S.C. § 112, First Paragraph.**

In the Office Action, claim 95 is rejected under 35 U.S.C. §112, first paragraph for lack of enablement. Applicant submits that the application as filed is fully enabled to support the present claim.

The Applicant asserts that the specification as disclosed compiles with 35 U.S.C. § 112 and does not require undue experimentation. The present invention discloses and enables a method to aid in predicting susceptibility of a human subject to development of an estrogen hormone responsive cancer in a mucosal epithelial tissue. The method includes quantitating the level of secreted dimeric/polymeric IgA, polymeric IgM and IgG1 in a secreted body fluid obtained from the subject suspected of having a cancer. The specification defines secreted dimeric/polymeric IgA, polymeric IgM and IgG1 on page 10 lines 13-21 as being active for inhibiting proliferation of a steroid hormone responsive cancer cell maintained in a suitable nutrient medium under cell growth promoting conditions, in the absence of an inhibition-reversing amount of the steroid hormone. The level of secreted dimeric/polymeric IgA, polymeric IgM and IgG1 in a secreted body fluid that is lower than wild-type levels is predictive of increased susceptibility of the human to development of the estrogen hormone responsive cancer in a mucosal epithelium.

The specification provide support for the quantitating the level of secreted dimeric/polymeric IgA, polymeric IgM and IgG1 which is active for inhibiting proliferation of a steroid hormone responsive cancer. The specification provides detailed examples of making and using the present invention, see examples 29-44 in the specification as filed. It is not necessary for the application to "...enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect." *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1338, 68 USPQ2d 1940, 1944 (Fed. Cir. 2003).

Applicants assert that when the factors to determine undue experimentation set forth in *In re Wands* are addressed the claimed invention is enabled so that any person skilled in the art can make and use the invention without undue experimentation. With regard to the quantity of experimentation necessary all necessary information is present in the specifications or known to a person of skill in the art. The specification provides direction and guidance including examples and results. Currently, those of skill in the art are PhDs, MS and MDs escalating the relative level of skill of those in the art. When these factors are taken as a whole it is clear that undue experimentation is not necessary; and thus, the specification is enabled to support claim 95.

Furthermore, the test is not whether any experimentation is necessary but if the experimentation is undue. The Action states that the levels of immunoglobulin vary as a function of the time of day and so forth and as a result there is undue experimentation. Applicant asserts that undue experimentation is not necessary and even if the levels were to fluctuate (which Applicant does not concede), it would still not result in undue experimentation. By analogy, a subject's blood pressure varies day by day and hour by hour as a result of many factors, yet it could not be argued that the determination of a subject's blood pressure and classification as high blood pressure or low blood pressure requires undue experimentation.

As such, the specification satisfies the written description requirement under 35 U.S.C. § 112, first paragraph. For the reasons mentioned above, the Applicant respectfully requests the withdrawal of the rejection under 35 U.S.C. § 112.

**Conclusion**

In light of the amendments, remarks and arguments presented above, Applicant respectfully submits that the claim in the Application is in condition for allowance. Favorable consideration and allowance of the pending Claim 95.

If the Examiner has any questions or comments, or if further clarification is required, it is requested that the Examiner contact the undersigned at the telephone number listed below.

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Respectfully submitted,



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